

# Exhibit

## “5”

# GYNECARE® TVT Retropubic System



## Retropubic benefits:

- > Over a decade of clinical data<sup>1</sup>
- > Long-term clinical efficacy, safety and innovation<sup>1</sup>

## Long-term clinical efficacy and safety

- > The longest follow up study of its kind<sup>1</sup>
- > No late onset adverse events in an 11 year follow-up study<sup>1</sup>
  - No tape erosion<sup>1</sup>
  - No tissue reactions<sup>1</sup>

## Proven safety demonstrated across multiple clinical studies

- > Low incidence of reported serious complications (<0.0004%)<sup>2</sup>
- > Low retention rate (<3%)<sup>3,4,5</sup>
- > Low risk of urethral erosion<sup>1,4,5</sup>

## Proven mesh

- > GYNECARE® TVT Retropubic System uses PROLENE® Polypropylene Mesh
  - clinically proven with over a decade of use in the treatment of SUI<sup>1</sup>

Sustainable success rates proven in an 11 year follow-up study

3% Failure

20% Improved

77% Cured

97% Overall Success<sup>1</sup>

Gynecare®  
**TVT Retropubic System**

Tension-free Support for Incontinence

# GYNECARE® TTV Retropubic System



- > Long-term clinical efficacy and safety.
- > 95.3% had negative cough stress test.
- > 90.2% had a negative pad test.
- > 90.2% regarded objectively cured.
- > 77% of the patients regarded themselves as cured.
- > No case of tape erosion.

*Summary of paper by C. G. Nilsson & K. Palva & M. Rezapour & C. Falconer (2008).*

Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence.

With an increasing life expectancy of women in the developed world the number of women suffering from stress urinary incontinence is growing rapidly.

The tension-free vaginal tape (TVT) procedure for treatment of female stress incontinence is the first modern minimally invasive mid urethra sling operation and the only one thus far with reports of cure rates in patient follow-up of 5 years or more.

## LONGTERM EFFECTIVENESS AND SAFETY WITH TVT

In a Nordic three-centre prospective observational cohort study, 90 women with primary stress incontinence had a TVT operation performed under local anaesthesia. The TVT procedures were performed between January 1st 1995 and August 15th 1996. Evaluation 11 years after the TVT operation included a 24 hour pad test, a stress test, physical examination, and a visual analog scale for assessing the degree of bother. Patient's global impression of cure was obtained and condition specific quality of life questionnaires were used. The aim of this study was to evaluate the longterm effectiveness and safety of the tension-free vaginal tape (TVT) procedure.

## NINETY PERCENT OBJECTIVELY CURED

Seventy-seven percent of the initial cohort of 90 women were alive and capable of cooperating 11.5 years after the TVT operation. Objective cure was defined as a negative stress test and a negative 24 hour pad test (less than 8 g per 24 h), while subjective cure was defined by the patient's global impression of her continence status.

The cough stress test was negative in 95.3% of the women and 90.2% had a negative pad test. Of these women, 90.2% had both a negative stress test and a negative pad test and thus regarded objectively cured.

Subjective cure by patients global impression was found in 77%, 20% as improved, and 3% thought the treatment had failed. Asked if experiencing leakage on straining 93% claimed they were dry and 97% were prepared to recommend the TVT operation to a friend.

## NO TAPE EROSION OR ADVERSE TISSUE EFFECTS

A gynaecological examination where careful attention was paid to detect tape erosion or adverse tissue effects caused by the polypropylene material.

No late-onset adverse effects of the operation were found, and no case of tape erosion was seen. The TVT procedure is safe and effective for more than 10 years.

## PROVEN SAFETY DEMONSTRATED ACROSS MULTIPLE CLINICAL STUDIES

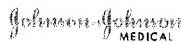
Many reports have shown that the TVT procedure is effective in many different groups of patients, with cure rates between 80% and 90% during follow-up periods of more than 3 years.

The results are reassuring and show that there is no decline in efficacy of the TVT procedure over time. Even though we are dealing with an aging population, 62% of the women of this trial were more than 60 years old at the time of their 11 years follow-up visit.

1. C. G. Nilsson & K. Palva & M. Rezapour & C. Falconer (2008) Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence. 2. Data on file; R & D Central File. 3. Lord I, Taylor J, Finn J et al. A randomized controlled equivalence trial of short-term complications and efficacy of tension-free vaginal tape and suprapubic urethral support sling for treating stress incontinence. British J Urol. 2006;98:367-376. 4. Araco F, Gravante G, Sorge R et al. TVT-O vs. TVT: a randomized trial in patients with different degrees of urinary stress incontinence. Int Urogynecol J 2008;19:917-926. 5. Rinne K, Laurikainen E, Kivellä A et al. A randomized trial comparing TVT with TVTO: 12 month results. Int Urogynecol J. 2008;19:1049-1054



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